REMARKS

Claims 1-7 are currently pending in the application. Claims 1 and 5-7 are in independent form.

The Examiner has requested clarification with regard to an entry of October 30, 2003. The text that was included was submitted to clarify an issue raised in the previous Office Action.

The Office Action notes an informality in claim 4. The informality has been corrected herewith.

Claim 4 stands rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action has held that the claim contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action has held that claim 4 generally recites an additional therapeutic agent and that there is no limitation as to what this agent could be. As stated in the Office Action, there is disclosure on page 12, lines 26-30 that the complex of the present invention can be co-administered with a therapeutic agent such as a chemotherapeutic. A chemotherapeutic agent is defined in Dorland's Illustrated Medical Dictionary, 25th Edition as "pertaining to chemotherapy", wherein chemotherapy is defined as the "treatment of disease by chemical agents; first applied to use of chemicals that affect the causative organism unfavorably, but do not harm the patient". In other words, it pertains to agents that are capable of attacking disease, but preferably do not harm the individual patient. This therefore, can be distinguished from <u>any</u> currently available therapeutic. Additionally, those of skill in the art are aware of appropriate therapeutic agents and chemotherapeutic agents. It is respectfully submitted that the disclosure of a chemotherapeutic agent is designed to characterize a type of chemotherapeutic agent, such that it is an agent that aids in the recovery from disease as opposed to any agent out there that does not cause harm. Individuals of skill in the art, especially those familiar with utilizing gold therapy and the variety of uses thereof, are very familiar with therapeutics and chemotherapeutics and as such, it would not be undue experimentation for the individuals to determine chemotherapeutics or other therapeutics that can be used in conjunction with a gold

containing compound. Additionally, as gold compounds are currently in use in conjunction with other therapeutic agents, it is not outside the scope of one of skill in the art to determine agents that are capable of providing therapy to a patient and using those in conjunction with the claimed compound. Since there is sufficient disclosure in the specification for the term therapeutic agent, reconsideration of the rejection is respectfully requested.

Claims 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, as being broader in scope than their enabling disclosure. The Office Action has held that claims 6 and 7 would not be objected to if the terms "preventing" and "arresting" were replaced by the terms "inhibiting" or "reducing." Such corrections have been made herewith and reconsideration of the rejection is respectfully requested.

Claims 5-7 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Office Action has held that the claims are confusing because the preamble recites "steps" but the body of the claim only recites a single step. In order to further prosecution, the claims have been amended to recite a single step and reconsideration of the rejection is respectfully requested.

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Komiya et al reference. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Komiya et al reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Komiya et al reference discloses a hydroxymethylphosphine ligand bound to a non-radioactive gold atom, which is in a solvent and is further complexed with nucleosides and is thus equivalent to the claimed complex because the compound includes gold, a pharmaceutically acceptable carrier (a solvent), and a therapeutic (nucleosides) as recited in the presently pending independent claims. However, as stated in response to the written description rejection, the therapeutics included in the complex of the present invention are intended to be limited to compounds that treat disease and such limitations are disclosed throughout the specification and specifically at page 12, lines 26-30. Since the Komiya et al reference

does not disclose the complex of the presently pending independent claims, the claims are patentable over the prior art and reconsideration of the rejection is respectfully requested.

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Chemical Abstracts 127:144328. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Chemical Abstracts 127:144328, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Chemical Abstracts disclose a hydroxymethylphosphine ligand bound to a gold atom, which is in a solvent and the solvent includes alcohol and is thus equivalent to the claimed complex because the compound includes gold, a pharmaceutically acceptable carrier (a solvent), and a therapeutic (alcohol) as recited in the presently pending independent claims. However, as stated in response to the written description rejection, the therapeutics included in the complex of the present invention are intended to be limited to compounds that treat disease and such limitations are disclosed throughout the specification and specifically at page 12, lines 26-30. Since the Chemical Abstracts do not disclose the complex of the presently pending independent claims, the claims are patentable over the prior art and reconsideration of the rejection is respectfully requested.

Claims 1-4 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Okuhama et al patent. Reconsideration of the rejection under 35 U.S.C. § 102(e), as anticipated by the Okuhama et al patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Okuhama et al patent discloses a hydroxymethylphosphine ligand bound to a gold atom, which is in water and the water can include EDTA and is thus equivalent to the claimed complex because the compound includes gold, a pharmaceutically acceptable carrier (water), and a therapeutic (EDTA) as recited in the presently pending independent claims. However, as stated in response to the written description rejection, the therapeutics included in the complex of the present invention are intended to be limited to compounds that treat disease and such limitations are disclosed throughout the specification and specifically at page 12, lines 26-30. Since

the Okuhama et al patent does not disclose the complex of the presently pending independent claims, the claims are patentable over the prior art and reconsideration of the rejection is respectfully requested.

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Katti et al. patent in view of the Fricker reference. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference. Reconsideration of the rejection is respectfully requested.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Katti, et al. patent discloses hydroxyalkylphospine-gold complexes and suggests their use as cancer chemotherapeutic agents. The Office Action acknowledges that the patent does not disclose that the complexes can contain non-radioactive gold. While the patent discloses the use of the term "gold" broadly, the exemplified and preferred embodiments all use radioactive species. The Office Action has indicated that the specification implies the use of non-radioactive pharmaceuticals as at least preferred embodiment.

When read more specifically, the specification discloses at column 1, lines 35-45, that compounds that contain gold contain gold isotopes and these isotopes have been implicated as an important basis in the design of tumor-specific radiopharmaceuticals for use in the diagnosis and therapy of human cancer. Thus the therapeutic applications do indicate that radioactivity is desired as the isotopes are being suggested by the prior art. Further, in column 2, lines 11-21, there is disclosed that gold 198 and gold 199 possess radionuclidic properties that make them attractive for use in formulating therapeutic radiopharamaceuticals. The Katti, et al. patent requires a radioactive radiopharmaceutical that can be used in treating individuals. However, there is no disclosure or suggestion that the radiopharmaceutical could be anything other than radioactive. Further, column 4, lines 33-35, there is disclosed that

the gold atom can be an isotope selected from the group including gamma and beta emitting isotopes. There is no disclosure that the gold atom could be anything other than a radioactive gold.

With regard to the Fricker reference, the Office Action states that it is well-known to use gold complexes in non-radioactive form for various types of therapies, particularly the treatment of arthritis and also in treating cancer. However, it is respectfully submitted that there is no indication in the prior art that non-radioactive gold can effectively be used for treating cancer. Compounds have been used containing non-radioactive gold in attempting to treat cancer, however, the toxicity reports from these studies have indicated that gold is not effective in treating cancer and instead is toxic. The indication of the Fricker reference would lead one to not utilize a gold compound as non-radioactive gold has demonstrated toxicity *in vivo*. In contradistinction, the presently claimed invention provides a non-toxic hydroxyalkylphosphine donor group bound to a non-radioactive gold atom that forms a stable gold-like complex that is not toxic. There is no suggestion to use the gold complexes for treating cancer.

It is undisputed that non-radioactive gold has been used in treating arthritis. Gold complexes have been used to treat rheumatoid arthritis patients because the gold complexes are known to help alleviate symptoms and potentially put the arthritis in remission. There is no clinical analysis that forms a linkage between the treatment of arthritis and the treatment of cancer. The individuals who have thus far utilized gold in treating cancer have had negative results and, in fact, have experienced toxicity problems. There is no indication, and in fact, there is a teaching away from utilizing gold in treating cancer. Accordingly, there is no suggestion, for the use of non-radioactive gold complexes in treating cancer. Reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of

the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Amy E. Rinaldo, Reg. No. 45,791
30500 Northwestern Highway
Suite 410
Farmington Hills, Michigan 48334
(248) 539-5050

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Connie Herty